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MEDIGROUP, Inc.

JUL - 3 2007

510(k) Summary

Basic Information

Submitter:	Medigroup, Inc. 14 A Stonehill Road Oswego, IL 60543
Establishment Registration Number:	#1450420
Contact:	John A. Navis, President
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Date of Submission	March 13, 2007

Device Information

Trade Name:	Flex-Neck® ARC™ PD Catheter & Accessories
Common Name:	Peritoneal Dialysis Catheter & Accessories
Classification Name:	78 FJS, accessory.
Class:	II

Predicate Devices

510(k) 862046 Swan-Neck™ PD Catheter issued June 19, 1986
510(k) 970159 Flex-Neck® PD Catheter issued September 5, 1997
510(k) 031351 Flex-Neck® PD Catheter, Infant, issued September 17, 2003

Product Description

This device consists of a peritoneal dialysis catheter and accessories. The catheter is made of long-term, implantable grade silicone tubing with a radiopaque strip, and one or two cuffs made of polyester felt. The coiled catheter has a permanent bend and is available in three adult variations, three pediatric/adolescent variations, and two infant variations. Included in the catheter package is a set of stencils (right and left) to help determine which configuration of catheter to implant and to assist the physician to locate the optimum primary and secondary incision sites. (Note: In addition to being packaged with each catheter, this stencil set will be sold sterile, packaged by itself, so the physician or other qualified personnel can use it in a clinical setting prior to the implantation.) Also packaged with the catheter will be a surgical grade marking pen, a plastic catheter connector and cap, and a packet of water-soluble lubricating gel.

Intended Use

The Flex-Neck® ARC™ catheter is designed for adults, children, and infants for whom peritoneal dialysis has been decided to be the mode of treatment by a physician. This catheter will be chosen by the physician who desires the faster flow-rates of the Flex-Neck® conventional PD catheter as well as the uniformity of the permanent bend provided by the Swan-Neck™ catheter. The addition of accessories packaged with the catheter will enhance the implantation and use of the catheter.

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Substantial Equivalence

The new Flex-Neck® ARC™ catheter has the same indications for use as the two predicate devices, the Flex-Neck® "classic" catheter and the Swan-Neck™ catheter. All three catheters are to be implanted in a patient needing peritoneal dialysis in order to provide access for peritoneal dialysis fluid infusion and drainage. All three are a silicone tube, with one or two cuffs for anchoring in the rectus muscle, ending in a coil. The Flex-Neck® catheters (both the "classic" style and the new ARC™ design) have a larger internal diameter than the Swan-Neck™ catheter which provides a faster flow rate for the fluid. The Flex-Neck® "classic" style is bendable into variable caudally directed exit sites, whereas the Flex-Neck® ARC™ and the Swan-Neck™ catheters have a 30° permanent bend. The Flex-Neck® ARC™ catheter therefore combines advantages of both predicate devices.

Testing

The twenty-year history of the Swan-Neck™ catheter with its permanent bend, and the ten-year history of the Flex-Neck® "classic" catheter with its larger internal diameter and variable bend have validated the design. High usage of catheters with this design further validates that a coiled silicone tube with a permanent bend is the catheter of choice for many physicians. See also three articles/ studies from 1985, 1995, and 1996 in Appendices F.1, F.2, F.3 which confirm the benefit of a permanently bent peritoneal dialysis catheter. Additional studies are referenced in F.4. Because of the longevity and success of the two predicate devices, no further studies have been done for this submission.

Conclusions

The Flex-Neck® ACR™ peritoneal dialysis catheter will function as designed and intended. It will provide a faster flowing access for peritoneal dialysis fluid and give the physician a bent tunnel portion to maintain a permanent arcuate tunnel/exit site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2007

Mr. John A. Navis
President
Medigroup, Inc.
14 A Stonehill Road
OSWEGO IL 60543-9400

Re: K070730
Trade/Device Name: Flex-Neck® ARC™ Catheter and Accessories
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: June 1, 2007
Received: June 4, 2007

Dear Mr. Navis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070730

Indications for Use

510(k) Number (if known): K070730

Device Name: Flex-Neck® ARC™ Peritoneal Dialysis Catheter & Accessories

Indications For Use:

If a patient is a suitable candidate for peritoneal dialysis (PD) therapy, the Flex-Neck® ARC ™ peritoneal dialysis catheter can be implanted either surgically, laparoscopically, or peritoneoscopically for acute or chronic peritoneal dialysis.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070730